PDL-MH Workgroup Summary
January 7, 2005

The Workgroup's task is to work with the Department to provide input and advice to address the concerns of the Mental Health community regarding the Preferred Drug List. The main topics discussed are:

- Grandfathering
- Appeals process
- Education / Outreach
- Off-label usage
- Algorithms
- Evaluation of PDL Impact

The workgroup members include: Gary Mihelish D.M.D. (NAMI), Jim Fitzgerald (Central Service Area Authority), Mignon Waterman (Advocate), Bob Keenan (Legislature), Mark Eichler R.Ph. (MPQHF), Julie Maggiolo M.D. (MT State Hospital Psychiatrist); Bobbi Renner Ph.D. (Quality Assurance Manager AMDD); Jennifer Lynch (Consumer), Chuck Hunter (Administrator, HRD), Duane Preshinger (Bureau Chief, HRD)

Below is a short discussion on each of the topics raised by the workgroup and the final decision or recommendation of the Department.

1. Grandfathering

The Department outlined information from several states concerning what they do in the grandfather process for their PDL list if it includes mental health drugs. The concern raised by the Mental Health advocates included the impact on the patients who are stabilized on medications that the Department indicates as being "non-preferred".

After hearing the concerns from the Mental Health clients and advocates, The Department made the decision to implement the PDL in the typical and atypical anti-psychotics drug classes using the following methodology.

- Typical Anti-psychotics:
    i. The Department will continue to manage the typicals using the current format in place since July 2001. Clients are required to use generic medications when available. For brand name medications to be dispensed, the physician must receive a Prior Authorization from the Drug PA Unit.
- Atypical Anti-psychotics:
    i. The Department will prefer all drugs currently in the class to allow providers to continue to prescribe medication without any prior authorization requirements. This will ensure all existing clients continue with their current drug regimens even when the PDL is implemented.

For all new medications, the drug will be classified as non-preferred until the Formulary Committee has an opportunity to review and make a recommendation to the Department regarding their inclusion on the PDL.

The Formulary Committee is also responsible to make recommendation to the Department regarding the Grandfathering of medications on a class-by-class basis. At the December Formulary Committee meeting, they made recommendations to the Department to grandfather all patients currently taking medication in the following classes: Antidepressants: Selective Serotonin Reuptake Inhibitors (SSRI's); Antidepressants (Novel); Stimulants (ADHD Agents) and Cholinesterase Inhibitors (Alzheimer's Agents). The Department

accepted all recommendations from the Formulary Committee and the PDL is now posted on the Montana Medicaid website. The address is: www.mtmedicaid.org.

2. Appeals process

There was substantial discussion regarding the appeals process and how it will be changed in order to provide a timely turn around with the prescribed medications. Geralyn Driscoll, DPHHS attorney, provided a handout and spoke about a grievance system that will protect the rights of clients and comply with Medicaid requirements and state law. Currently, we have a two-step review process through the Department Fair Hearing process. Upon a Fair Hearing being requested, the first step is an informal review between the client and the Department program officer. This review allows both parties to explain their case and, if necessary, provide additional documentation to resolve the case prior to scheduling a formal hearing. If requested, an additional party may represent either the client or the Department.

If the parties are unable to reach an agreement, the client is able to request a fair hearing. The Fair Hearing is a formal hearing with a hearing officer assigned through the Office of Fair Hearings operated within the Departments Quality Assurance Division. In the Fair Hearing process (usually held via telephone), the client and the Department are responsible for presenting hearing exhibits and testimony to the hearing officer. The Hearing Officer is responsible for issuing a Decision and Order which either rules for the client or the Department. If either of the parties appeals this ruling, the next appeal goes to the Board of Public Assistance. An appeal after that level goes to District Court.

All the workgroup members understand the need for a quick process that also takes into consideration the medical needs of the patients. The following Department proposal is in response to the concerns raised by the Mental Health community regarding the appeals process. The Montana Medicaid Program will apply the following procedures to assure the prompt resolution of prescriber and client grievances or appeals relative to medication denials.

A. All denied claims at the point of sale (POS) would result in one of the following occurring. Patients will be informed by the pharmacy of the initial denial and course of action:
    a. The pharmacist would either: contact the provider and request a change to a Medicaid preferred product that can be filled immediately; or contact the prior authorization unit to request a PA based on prior pharmacy claims history indicating the patient meets the criteria for a PA. If one of the above requests were approved, the script would be filled immediately. If not, the following process would be followed.
    b. The pharmacy, prescriber or prescriber's designee may mail, fax or phone the Medicaid Drug PA contractor to request the PA. If approved, the contractor will communicate this authorization verbally to the prescriber and dispensing pharmacy.
    c. The contractor may require additional clinical information to make their determination. The decision to either approve or deny the request will be made within one business day of receipt of all requested information.
        i. If approved, the contractor will call the dispensing pharmacy and prescriber with the authorization.
        ii. If the PA is denied because the patient does not meet Medicaid criteria and the prescriber wants to request a special review, they will fax or mail a letter describing the special circumstances for the individual patient and their request for the drug. The letter would then be presented to the Drug Use Review Board (DURB) for special consideration. If approved see (c)(i).
        iii. If denied by the DURB, a final determination of denial letter with the applicable hearing rights will be either faxed or mailed to the provider and mailed to the patient from the PA contractor.

B. If the patient and/or prescriber wish to further challenge the denial, a Fair Hearing may be requested. To request a hearing, either the patient or prescriber must submit a written request to the Office of Fair Hearings (within 90 days of the final determination of denial letter for the patient and within 30 days for the prescriber). Requests should be submitted to:

DPHHS
Office of Fair Hearing
PO Box 202953
Helena Mt 59620-2953

Medicaid patients may represent themselves in the hearing process, or may be represented by legal counsel, a relative, a friend or other spokesperson. The patient may be eligible to receive free legal assistance from the Montana Legal Services Association. For more information, they may contact the nearest legal services office. If they have a disability, they may request reasonable accommodation in the hearings process by contacting the Hearings Officer.

As is currently the policy, the Pharmacy can provide clients an emergency 72-hour supply of the requested medication while the prior authorization process is taking place. Once the final determination has taken place, Medicaid will no longer pay for the requested medication unless the PA denial is overturned through the hearing process.

3. Education / Outreach

The Department contract with First Health outlines the educational component of the PDL. In addition to the Department, First Health is also responsible for educating the prescribers regarding the PDL. Prior to implementation, the Department will have 8 regional trainings regarding the PDL. The trainings will be held in Great Falls, Billings, Helena, Butte, Missoula, Kalispell, Miles City and Glasgow. In addition to the trainings, Department and First Health staff will contact prescribers directly regarding the client drug utilization. Other education components include provider profiling which notify the prescribers which of their clients are taking non-preferred medications to advise them to either request a prior authorization (if medically indicated) or advise them to switch the client to the preferred medication. Many manufacturers will also distribute information to prescribers regarding the Medicaid status of they medications.

The Department is also designing a brochure for Pharmacies that will be available to clients that outline the PDL process and notify the clients of their appeal rights. This brochure will also be available at the Office of Public Assistance Officers and be included in the new enrollments packets for Medicaid clients advising them of the PDL and its impact on their prescribed medications. The draft document has been included in this mailing.

When the PDL is initially implemented, the Pharmacy Point-of-Sale (POS) system will have soft edits in place to advise the pharmacies that the client is receiving a non-preferred medication and they should contact the prescriber to either switch the prescription or start the prior authorization process. This edit will be in place at least one month prior to implementing the hard edit. During the soft edit time frame, Medicaid will continue to cover the non-preferred medication. The next phase of the PDL implementation is the hard edit. Once the hard edit is placed on the system, the client must receive a PA in order for Medicaid to cover the non-preferred medication. The soft edit will be in place at least one month prior to implementation of the hard edit.

4. **Off label usage**

As is currently the practice, prescribers can continue to prescribe drugs for indications they are not currently approved for by the FDA. With the implementation of the PDL, this will continue to be the case.

5. **Algorithms**

The Department is moving forward with a contract with Comprehensive NeuroScience (CNS). The CNS service is based on readily available Medicaid pharmacy claims data. The claims analysis is the basis for the CNS prescriber education and outlier management system called the Behavioral Health Pharmacy Management System (BPM). Through its BPM, CNS seeks to improve the quality of behavioral health prescribing practice, improve patient compliance with therapies and reduce behavioral health drug spend trend rates. To date, nineteen other states are currently using CNS to provide education to providers regarding behavioral medications. Because the BPM focuses on quality improvement, clinicians and advocates generally support it.

The BPM analysis focuses on specific areas called "edits" to compare prescriber practice with best-practice prescribing guidelines. Some examples of these edits include:

- Prescribing two or more atypical antipsychotic medications to a patient concurrently;
- Excess dosing, as well as prescribed dosages below recognized therapeutic levels;
- Children who are prescribed three or more behavioral health drugs concurrently;
- Patients who receive antipsychotic prescriptions from multiple prescribers concurrently;
- Failure of high-risk patients to fill behavioral health antipsychotic prescriptions in timely fashion; and
- Use of two or more behavioral health drugs from the same therapeutic class.

The educational letters are sent out monthly to prescribers. Physician peer reviewers are selected from Montana to work with prescribers who continue to deviate from best practice guidelines over a period of months. The functions performed by CNS will be integrated into the current function of the DUR Board / Formulary Committee to allow for a seamless operation in regards to the education of Montana prescribers.

6. **Evaluation of PDL Impact**

This is the final item for discussion by the workgroup. It is the intent of the Department for the PDL to have a minimal impact on the Medicaid patients. In order to track any possible cost shifts due to the implementation of the PDL five key indices must be monitored.

- Emergency Room Visits
- Hospital Admissions
- Mental Health admissions
- Psychiatric Claims
- Physician Claims
- Pharmacy Claims

The Department will establish a historical baseline of the listed indicators and project a growth rate prior to the implementation date of the PDL. After PDL implementation the above indices will be monitored to detect possible cost shifts within the Medicaid program. Consideration will be made regarding changes within the respective programs that are tentatively planned.